Senator Feinstein Urges Pentagon to Step Up Efforts to Track Medical Damage Caused by Anti-Malarial Drug

June 2, 2004

Washington, DC – With evidence growing of serious side effects in the military from the anti-malarial drug Lariam (mefloquine), including seven members with permanent brainstem and vestibular damage, U.S. Senator Dianne Feinstein (D-Calif.) urged the Defense Department to step up efforts to track the side effects and provide treatment related to use of the drug.

In a letter to Secretary of Defense Donald Rumsfeld sent Tuesday, Senator Feinstein asked that the Pentagon announce a timeline for a study assessing the drug's side effects. Additionally, the Senator requested that the department improve consistency in recording medications in medical records, conduct pre- and post-deployment health assessments and establish a mechanism that will allow those experiencing side effects to receive timely, effective and appropriate diagnoses and treatment without fear of reprisal.

In a separate letter to Veterans' Affairs Department Secretary Anthony Principi, Senator Feinstein urged his department to work closely with the Department of Defense and to encourage the Pentagon to move forward expeditiously with its study of Lariam (mefloquine).

Following is the text of the letters to Defense Department Secretary Rumsfeld:

> "I am writing to follow up on my previous letters regarding the Department of Defense (DoD)'s use of Lariam (mefloquine) as an antimalarial drug. As you are probably aware, new evidence further substantiating the dangers associated with this drug came to light last week. Five additional military service members have been diagnosed with permanent brainstem and vestibular damage from mefloquine toxicity. This brings the present total of diagnosed service members to seven.
>
> Given the gravity of this diagnosis I think it is necessary that the DoD immediately implement a program that will allow soldiers to report side effects, be evaluated, diagnosed and treated without fear of reprisal and that reporting side effects would not have a negative impact on their military service or career. This is especially crucial for service members since contraindications listed on mefloquine's package labeling include concurrent general anxiety disorders, such as Post Traumatic Stress Disorder (PTSD) or other major psychiatric disorders. The sooner a diagnosis of drug toxicity is made and an affected service member taken off the medication, the less the potential for harm and the sooner treatment can begin to mediate the impact of serious side effects.

The guidelines developed by the Deployment Health Clinical Center for clinicians, unit leaders and service members and their families highlight my concerns, warning that "normal reactions to deployment and combat stress may be similar to both the common and behavioral side effects of mefloquine." Thus it is imperative that accurate diagnoses by trained professionals are made as soon as symptoms of mefloquine toxicity are evident.

I understand that the military requires pre- and post-deployment health assessments. However, given that medications are not always documented in service members' medical records, as was true in the case of the seven affected service members, I think that it is necessary that DoD begin a process of consistent pre- and post-deployment health assessments. These health assessments need to be conducted within the prescribed timeframes and reviewed by medical professionals trained to ensure that service members are given appropriate and timely treatment for deployment-related conditions.

Additionally, while the Department's decision to conduct a study on the effects of mefloquine under deployment and post-deployment conditions is a positive step, I think it is essential that the study is planned, designed and conducted with a panel of experts. These experts should represent a variety of medical disciplines including but not limited to psychiatry, neurology, pharmacology and pathology. Further, the panel should include representatives from the Department of Veterans Affairs, the Food and Drug Administration, the Centers for Disease Control and Prevention, National Institutes of Health among others. It is also my hope that the information from the seven service members diagnosed with permanent brainstem and vestibular damage from mefloquine toxicity be included in DoD's study.

Finally, I sincerely believe that the DoD needs to quickly establish a timeline for this study. There is already sufficient evidence in drug labeling to make the causal link between mefloquine and many of the serious adverse events experienced by service members as the basis for a medical diagnosis or as the basis for assessing disability. Although I am interested in the study results, I think the first priority needs to be providing affected soldiers and their families with the resources they need to obtain the treatment and support necessary to recover lost capabilities the best that they can.

I thank you in advance for your attention to this matter, and look forward to your reply."

Following is the text of the letter sent to Veterans' Affairs Secretary Principi:

"I am writing to express my concerns about the Department of Defense (DoD)'s use of the drug Lariam (mefloquine) as an antimalarial drug. As you are probably aware, new evidence further substantiating the dangers of this drug came to light last week. Seven service members have now been diagnosed with permanent brainstem and vestibular damage from taking this drug despite the fact that alternative drugs might have been chosen to prevent infection.

Given the gravity of this diagnosis I think it is necessary that the DoD immediately implement a program that will allow soldiers to report side effects and be evaluated, diagnosed and treated without fear of reprisal and that reporting

side effects will not negatively affect their military service or careers. This is especially crucial for service members since a contraindication listed on mefloquine's package labeling is a concurrent general anxiety disorder, such as Post Traumatic Stress Disorder (PTSD) or other major psychiatric disorders. The sooner a diagnosis of drug toxicity is made and an affected service member taken off the medication, the less the potential for harm and the sooner treatment can begin to mediate the impact of serious side effects.

The guidelines developed by the Deployment Health Clinical Center for clinicians, unit leaders and service members and their families highlight my concerns, warning that "normal reactions to deployment and combat stress may be similar to both the common and behavioral side effects of mefloquine." Thus it is imperative that accurate diagnoses by trained professionals are made as soon as symptoms of mefloquine toxicity are evident.

I understand that the military requires pre- and post-deployment health assessments. However, given that medications are not always documented in service members' medical records, as was true in the case of the seven affected service members, I think that it is necessary that DoD begin a process of consistent pre- and post-deployment health assessments. These health assessments need to be conducted within the prescribed timeframes and reviewed by medical professionals trained to ensure that service members are given appropriate and timely treatment for deployment-related conditions.

Additionally, while the Department's decision to conduct a study on the effects of mefloquine under deployment and post-deployment conditions is a positive step, I think it is essential that the study is planned, designed and conducted with a panel of experts. These experts should represent a variety of medical disciplines including but not limited to psychiatry, neurology, pharmacology and pathology. Further, the panel should include representatives from the Department of Veterans' Affairs (VA), the Food and Drug Administration, the Centers for Disease Control and Prevention, National Institutes of Health, among others. The involvement of the VA is essential as the VA's health care system is likely to be the first line of treatment for service members who have returned from active duty. In addition, the VA will bear the cost and burden of treatment and rehabilitation for service members with mefloquine toxicity.

As such, I ask for your assistance in encouraging DoD to quickly establish a timeline for this study. There is already sufficient evidence in drug labeling to make the causal link between mefloquine and many of the serious adverse events experienced by service members as the basis for a medical diagnosis or as the basis for assessing disability. Although I am interested in the study results, I think the first priority needs to be providing affected soldiers and their families with the resources they need to obtain the treatment and support necessary to recover lost capabilities the best that they can.

I thank you in advance for your attention to this matter, and look forward to your reply."

###